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Drug Manufacturers' Recommendations and the Common Knowledge Rule to Establish Medical Malpractice

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Drug Manufacturers' Recommendations and the Common Knowledge Rule to Establish Medical Malpractice

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I. INTRODUCTION

All prescription drugs cause side effects¹ and all are considered toxic.² "There is no such thing as absolute safety in drugs. There are some drugs that are less liable to cause a harmful reaction than others, but *people die every year from drugs generally regarded as innocuous.*"³ A conservative estimate⁴ is that 3 to 5 percent of all

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1. DEP'T OF HEALTH, EDUC. AND WELFARE, PUB. NO. (OS) 73-88, REPORT OF THE SECRETARY'S COMM'N ON MEDICAL MALPRACTICE 24 (1973) [hereinafter cited as REPORT OF THE SECRETARY'S COMM'N].

2. 2 S. PEGALIS & H. WACHSMAN, AMERICAN LAW OF MEDICAL MALPRACTICE § 9.7 (1981).

3. *Hearings on Drug Safety Before the Subcomm. on Intergovernment Relations of the House Comm. on Gov't Operations*, 88th Cong., 2d Sess. 147 (1964) (statement of George P. Larrick, Commissioner of FDA, 1961-1966) (emphasis added); Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 1 (1973).

4. Available data understates the number of actual injuries caused by drugs because reporting systems are erratic and incomplete. Merrill, *supra* note 3, at 4-5.

hospital admissions result from adverse reactions to prescription drugs.⁵ One study indicated that approximately 13 percent of all patients have an adverse reaction to drugs during hospitalization.⁶ Furthermore, at least one million people suffer severe reactions each year.⁷ A large number of adverse reactions are simply an "inevitable cost of the availability of prescription drugs."⁸ However, a large number of prescription drug reactions are also caused by medical negligence.⁹

In order to establish a *prima facie* case of medical negligence, a plaintiff must establish that the doctor owed him a duty of care¹⁰ and that the doctor breached that duty, thereby causing the plaintiff's injuries.¹¹ In most medical malpractice cases, the plaintiff must introduce expert testimony to establish both the standard of care that most doctors would have used under the same or similar circumstances¹² (and, in many states, in the same or a similar lo-

5. Pruzan, *Prescription Drug Liability in the Context of Washington Law*, 9 GONZ. L. REV. 707, 708 (1974).
6. Averbach, *Physician's Liability for Prescription Drugs*, 34 ST. JOHN'S L. REV. 535, 535 (1969). At least one study indicates that 30 percent of all hospitalized patients experience at least one adverse drug reaction. 1 S. PEGALIS & H. WACHSMAN, *supra* note 2, at § 1.9.
7. Merrill, *supra* note 3, at 3 n.7. This figure may be as high as three million. 1 S. PEGALIS & H. WACHSMAN, *supra* note 2, at § 1.9.
8. Merrill, *supra* note 3, at 2. "[I]f health offers adventure; no one has a better chance to live dangerously than the ill who must take . . . [the drug manufacturers'] medicine." Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 TENN. L. REV. 363, 368 (1965).
9. It has been estimated that drug-related malpractice accounts for 10 percent of all medical negligence cases. Hirsh, *The Medicolegal Significance of the Package Insert*, 1977 MED. TRIAL TECH. Q. 143, 143-44. In a random sample of medical hospital records, close to 15 percent of iatrogenic injuries were caused by adverse drug reactions. REPORTS, STUDIES, AND ANALYSIS DEP'T OF HEALTH, EDUC., AND WELFARE, PUB. NO. (OS) 73-89, APPENDIX REPORT OF SECRETARY'S COMM'N ON MEDICAL MALPRACTICE 55 (1973). Iatrogenic injuries are those caused by errors of omission or commission by physicians. *Id.* at 51.
10. The physician's duty ordinarily depends on the existence of a doctor-patient relationship. See generally *Hiser v. Randolph*, 126 Ariz. 608, 617 P.2d 774 (Ariz. Ct. App. 1980); *Hurley v. Eddingfield*, 156 Ind. 416, 59 N.E. 1058 (1901); *Hoover v. Williamson*, 236 Md. 250, 203 A.2d 861 (1964). But see *Molien v. Kaiser Found. Hosps.*, 27 Cal. 3d 916, 616 P.2d 813, 167 Cal. Rptr. 831 (1980); *Renslow v. Mennonite Hosp.*, 67 Ill. 2d 348, 367 N.E.2d 1250 (1977). The existence of the physician-patient relationship is not dependent upon payment for the physician's services; the relationship arises once the physician undertakes to treat the patient. *Betesh v. United States*, 400 F. Supp. 238 (D.D.C. 1974); *Rule v. Cheeseman*, 181 Kan. 957, 317 P.2d 472 (1957).
11. See generally A. HOLDER, *MEDICAL MALPRACTICE LAW* ch. 2 (1978).
12. *Riedisser v. Nelson*, 111 Ariz. 542, 534 P.2d 1052 (1975); *Haisenleder v. Reeder*, 114 Mich. App. 258, 318 N.W.2d 634 (1982); *Cornfeldt v. Tongen*, 262 N.W.2d 684 (Minn. 1977); *Hart v. Steele*, 416 S.W.2d 927 (Mo. 1967). See generally King, *In Search of a Standard of Care for the Medical Profession: The "Accepted Practice" Formula*, 28 VAND. L. REV. 1213 (1975).

cality),¹³ and that the defendant doctor deviated from the customary practice of his peers, thus causing the plaintiff's injuries.¹⁴

However, in prescription drug cases, where the doctor has deviated from the clear and explicit instructions of the drug manufacturer, the doctor should be called upon to explain the reason for that departure, rather than to show merely that he followed the customary practice of other doctors. In addition, the expert testimony requirement should be relaxed to assist the plaintiff in establishing a *prima facie* case for a prescription drug injury caused by a physician's misuse of the product, through reliance on the drug manufacturer's recommendation.

II. THE IMPORTANCE OF THE DRUG MANUFACTURERS' RECOMMENDATION

All manufacturers are required to give adequate directions and warnings for the safe use of their products.¹⁵ A drug manufacturer has the same duty to warn as any other manufacturer and may be held to be negligent¹⁶ or liable under product liability¹⁷ for its fail-

13. The "locality rule" is a creature of the United States courts and has no equivalent in English jurisprudence. Fleming, *Developments in the English Law of Medical Liability*, 12 VAND. L. REV. 633, 641 (1959). The locality rule establishes that a doctor has the duty to exercise that degree of skill and care ordinarily employed by members of his profession under similar circumstances and located in the same or a similar locality. The justification for the locality rule was that it would be unfair to impose upon a small town doctor the standards for a metropolitan doctor who has greater opportunities of daily observation and more medical resources and facilities. Many jurisdictions still adhere to some form of the locality rule. See, e.g., *Kronke v. Danielson*, 108 Ariz. 400, 499 P.2d 156 (1972); *Lauro v. Travelers Ins. Co.*, 261 So. 2d 261 (La. Ct. App. 1972); *Wentling v. Jenny*, 206 Neb. 335, 293 N.W.2d 76 (1980); *Pharmaseal Labs., Inc. v. Goffe*, 90 N.M. 753, 568 P.2d 589 (1977); *Bronwell v. Williams*, 597 S.W.2d 542 (Tex. Civ. App. 1980); *Jenkins v. Parrish*, 627 P.2d 533 (Utah 1981); NEB. REV. STAT. § 44-2810 (1978).

The current trend is to apply a national standard of care, the care a reasonably competent practitioner would use, acting in the same or similar circumstances, and to allow a jury to consider the availability of medical resources and facilities. See, e.g., *Shilkret v. Annapolis Emergency Hosp. Ass'n*, 276 Md. 187, 349 A.2d 245 (1975); *Brune v. Belinkoff*, 354 Mass. 102, 235 N.E.2d 793 (1968); *King v. Williams*, 276 S.C. 478, 279 S.E.2d 618 (1981); *Shier v. Freedman*, 58 Wis. 2d 269, 206 N.W.2d 166 (1973); OKLA. STAT. tit. 76, § 20.1 (Supp. 1983).

14. *Plutshack v. University of Minn. Hosp.*, 316 N.W.2d 1 (Minn. 1982); *Neese v. Shawnee Medical Center Hosp., Inc.*, 626 P.2d 1327 (Okla. 1981); *Denardo v. Carneval*, 297 Pa. Super. 484, 444 A.2d 135 (1982).

15. *Barber v. General Elec. Co.*, 648 F.2d 1272 (10th Cir. 1981). See generally J. BEASLEY, *PRODUCTS LIABILITY AND THE UNREASONABLY DANGEROUS REQUIREMENT* ch. 16 (1981); W. KIMBLE & R. LESH, *PRODUCTS LIABILITY* § 191 (1979).

16. *Smith v. E.R. Squibb & Sons, Inc.*, 405 Mich. 79, 273 N.W.2d 476 (1979); *Michael v. Warner/Chilcott*, 91 N.M. 651, 579 P.2d 183 (1978).

17. *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969); *Hamilton v. Hardy*,

ure to warn of known hazards connected with foreseeable uses of its products.¹⁸ In the products liability context, prescription drugs, which always carry a "medically recognizable risk" of injury, are usually classified as "unavoidably unsafe products."¹⁹ However, the overall public benefit derived from their use justifies the marketing of the drugs. Therefore, as long as the drugs are accompanied by proper warnings and directions, they are not considered defective and the manufacturer is not strictly liable for injuries caused by their use.²⁰

The duty to warn extends to those persons the manufacturer should reasonably expect to use or to be endangered by the product.²¹ Although it is the patient who will ultimately use or be endangered by a prescription drug, the manufacturer must warn the prescribing practitioner, rather than the patient, because the practitioner is the only party able to evaluate and balance the dangers of the drug against the benefits of its use.²² A warning to the medical profession is considered to be the only effective means by which a warning can protect the patient.²³ Once the physician is

37 Colo. App. 375, 549 P.2d 1099 (1976); *Baker v. St. Agnes Hosp.*, 70 A.D.2d 400, 421 N.Y.S.2d 81 (1979).

18. *Moran v. Faberge, Inc.*, 273 Md. 538, 332 A.2d 11 (1975); *Smith v. United Gypsum Co.*, 612 P.2d 251 (Okla. 1980).

19. RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965). "All consumers of prescription drugs serve as guinea pigs for the pharmaceutical industry, for every new drug remains basically 'experimental' even after it has been approved for general use." Merrill, *supra* note 3, at 20.

20. RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965).

21. *Griggs v. Firestone Tire & Rubber Co.*, 513 F.2d 851 (8th Cir.), *cert. denied*, 423 U.S. 865 (1975); *West v. Broderick & Bascom Rope Co.*, 197 N.W.2d 202 (Iowa 1972). See generally W. KIMBLE & R. LESHNER, *supra* note 15, at § 202.

22. *Dyer v. Best Pharmacal*, 118 Ariz. 465, 577 P.2d 1084 (Ariz. Ct. App. 1978); *Love v. Wolf*, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (Cal. Dist. Ct. App. 1964); *Richards v. Upjohn Co.*, 95 N.M. 675, 625 P.2d 1192 (N.M. Ct. App. 1980). See generally J. BEASLEY, *supra* note 15, at § 202. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-92 (1976), defines a prescription drug as one that "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under [a physician's supervision]." 21 U.S.C. § 353(b)(1)(B) (1976). Adequate information on proper use must be conveyed to the consumer for over-the-counter drugs, or the physician in the case of prescription drugs. 21 U.S.C. §§ 352-53 (1976).

23. *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121 (9th Cir. 1968); *Dunn v. Lederle Labs.*, 121 Mich. App. 73, 328 N.W.2d 576 (1982). The manufacturer's warning to the doctor is considered effective, except where a vaccine is dispensed at mass clinics, when there is no physician balancing the individual patient's risks, *Reyes v. Wyeth Labs.*, 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974); *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121 (9th Cir. 1968); *Cunningham v. Charles Pfizer Co.*, 532 P.2d 1377 (Okla. 1974); and except in the case of oral contraceptives. 21 C.F.R. § 310.501(a) (1983). In both of these instances, the warning must be given directly to the patient in order to be effective.

warned, the duty to use the drug properly and to explain any risks to the patient is incumbent upon the physician.²⁴

Inasmuch as the drug manufacturer's duty to warn is directed toward the physician, most of the litigation against manufacturers for injuries caused by prescription drugs deals with the adequacy of the warnings given to the medical profession.²⁵

The duty of the ethical drug manufacturer to warn extends, then, to all members of the medical profession who come into contact with the patient in a decision-making capacity. To satisfy the duty, the manufacturer *must utilize methods of warning which will be reasonably effective*, taking into account both the seriousness of the drug's adverse effects and the difficulties inherent in bringing such information to the attention of a group as large and diverse as the medical profession. . . . The warning should be sufficient to apprise the general practitioner as well as the "unusually sophisticated medical man" of the dangerous propensities of the drug. . . . *In short, "it is incumbent upon the manufacturer to bring the warning home to the doctor."*²⁶

The drug manufacturer's duty is a continuous one; the manufacturer must keep testing the product and notify the medical profession of any newly discovered side effects from the drug's use.²⁷

24. *Dyer v. Best Pharmacal*, 118 Ariz. 465, 577 P.2d 1084 (Ariz. Ct. App. 1978); *McKee v. Moore*, 648 P.2d 21 (Okla. 1982). *See generally* 2 S. PEGALIS & H. WACHSMAN, *supra* note 2, at § 9.14. Although the drug manufacturer may be held liable under a products liability theory for any injuries related to use of the drug, physicians, who indirectly supply the patient with the drug, are generally exempt from the doctrine of products liability because the essence of the transaction is considered a professional service, rather than a sale of goods. *See, e.g.*, *Barton v. Owen*, 71 Cal. App. 3d 484, 139 Cal. Rptr. 494 (Cal. Ct. App. 1977); *Silverhart v. Mount Zion Hosp.*, 20 Cal. App. 3d 1022, 98 Cal. Rptr. 187 (Cal. Ct. App. 1971); *Magrine v. Krasnica*, 94 N.J. Super. 228, 227 A.2d 539 (Hudson County Ct. 1967), *aff'd*, 100 N.J. Super. 223, 241 A.2d 637 (N.J. Super. Ct. App. Div. 1968), *aff'd*, 53 N.J. 259, 250 A.2d 129 (1969); *Hoven v. Kelleble*, 79 Wis. 2d 444, 256 N.W.2d 379 (1977). Recent cases are beginning to suggest that providers of medical care should be held strictly liable when patients are injured by a defective product. *See, e.g.*, *Grubb v. Albert Einstein Medical Center*, 255 Pa. Super. 381, 387 A.2d 480 (Pa. Super. Ct. 1978) (hospital held to strict liability).
25. *See, e.g.*, *Love v. Wolf*, 249 Cal. App. 2d 822, 58 Cal. Rptr. 42 (Cal. Ct. App. 1967); *Richards v. Upjohn Co.*, 95 N.M. 675, 625 P.2d 1192 (N.M. Ct. App. 1980); *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 528 P.2d 522 (1974); *Incolingo v. Ewing*, 444 Pa. 263, 282 A.2d 206 (1971); *Merrill*, *supra* note 3, at 40-49; *Pruzan*, *supra* note 5, at 708-09 nn.7-9. *See generally* Keeton, *Products Liability—Drugs and Cosmetics*, 25 VAND. L. REV. 131 (1972); Rheingold, *Products Liability—The Ethical Drug Manufacturers's Liability*, 18 RUTGERS L. REV. 947 (1964).
26. *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 388, 528 P.2d 522, 529 (1974) (citations omitted) (emphasis added). *Accord* *Richards v. Upjohn Co.*, 95 N.M. 675, 625 P.2d 1192 (N.M. Ct. App. 1980).
27. *Braun v. Roux Distrib. Co.*, 312 S.W.2d 758 (Mo. 1958); *Baker v. St. Agnes Hosp.*, 70 A.D.2d 400, 421 N.Y.S.2d 81 (N.Y. App. Div. 1979); 21 C.F.R. §§ 310.300-.301, 314.8 (1983). *See generally* W. KIMBLE & R. LESHAR, *supra* note 15, at § 205.

The notification of any new dangers associated with a drug must call specific attention to the danger and must reach the doctor promptly.²⁸ If necessary, the drug manufacturer has the duty to send individual letters, commonly called "Dear Doctor Letters," to all practicing physicians in order to warn of newly discovered side effects, or of contraindications associated with the use of an established drug.²⁹ The drug manufacturer's stringent burden under products liability law helps to ensure that physicians will receive complete and accurate information before they prescribe drugs.

A proper warning is useless unless it is read and followed by the physician. The law of products liability acknowledges this fact and provides that where a "warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in a defective condition, nor is it unreasonably dangerous."³⁰ Furthermore, under products liability law, failure to follow adequate instructions is considered misuse which bars a plaintiff's recovery.³¹ The caselaw regarding the sufficiency of warnings on prescription drugs certainly indicates that the physician has the duty to read the drug manufacturer's warnings and to adhere to them under most circumstances. Indeed, it has been argued that a doctor who does not follow the recommendations has misused the product; and that such misuse is an intervening cause which relieves manufacturers from liability for the patient's injuries.³²

In addition to the multitude of products liability cases which indicate that a physician has the duty to follow the manufacturer's recommendations, the substantial federal control exercised over the marketing of drugs also indicates that the physician has such a

28. *Baker v. St. Agnes Hosp.*, 70 A.D.2d 400, 406, 421 N.Y.S.2d 81, 85-86 (N.Y. App. Div. 1979).

29. *Yarrow v. Sterling Drug, Inc.*, 263 F. Supp. 159 (D.S.D. 1967), *aff'd*, 408 F.2d 978 (8th Cir. 1969); *Baker v. St. Agnes Hosp.*, 70 A.D.2d 400, 421 N.Y.S.2d 81 (N.Y. App. Div. 1979).

30. RESTATEMENT (SECOND) OF TORTS § 402A comment j (1965).

31. *Pinto v. Clairol, Inc.*, 324 F.2d 608 (6th Cir. 1963); *Proctor & Gamble Mfg. Co. v. Langley*, 422 S.W.2d 773 (Tex. Civ. App. 1967). *See generally* W. KIMBLE & R. LESHNER, *supra* note 15, at § 198.

32. *See, e.g., Dunn v. Lederle Lab.*, 121 Mich. App. 73, 328 N.W.2d 576 (1982). "Causation is broken between the manufacturer and patient when the doctor disregards warnings." *Dyer v. Best Pharmacal*, 118 Ariz. 465, 468, 577 P.2d 1084, 1087 (Ariz. Ct. App. 1978). "[A] drug manufacturer cannot be required legally to foresee that a licensed physician will disregard express warnings regarding a drug's use." *Id.* at 469, 577 P.2d at 1088. However, a doctor's negligence in failing to consult the most recent literature on a drug's use has been considered foreseeable. Where the physician's negligence is foreseeable, a court may find that it is not an intervening cause sufficient to cut off the manufacturer's liability. *See, e.g., Richards v. Upjohn Co.*, 95 N.M. 675, 625 P.2d 1192 (N.M. Ct. App. 1980); *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206 (1971).

duty.³³ Since 1938, the Food and Drug Administration (FDA) has had the authority to forbid the marketing of any unsafe drug.³⁴ In 1961, the FDA gained additional power to ensure that drugs were effective, as well as safe, when used as recommended.³⁵ Prior to marketing, any new drug has to be approved by the FDA. Furthermore, the New Drug Application (NDA) must demonstrate the safety of the drug by adequate testing and prove by "substantial evidence" that the drug will have the claimed effect.³⁶ "Substantial evidence" is defined as:

evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have³⁷

Although the drug manufacturer is responsible for the actual testing of all new drugs, the FDA enumerates the types of tests which must be performed before any new drug may be approved.³⁸ The FDA, therefore, acts as an overseer to ensure that there is scientific proof in support of the safety and efficacy of any new drug.³⁹

In 1961, the FDA also promulgated the "full disclosure" regulation, which requires proper labeling of a prescription drug through package inserts.⁴⁰ According to the regulation, the package insert must contain:

adequate information for [the drug's] use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended⁴¹

The package insert is actually prepared by the drug manufacturer

33. See 21 U.S.C. §§ 301-92 (1976); Comment, *The Food and Drug Administration: Law, Science and Politics in Evaluation and Control of New Drug Technology*, 67 Nw. U.L. REV. 858 (1973); Comment, *Package Inserts for Prescription Drugs as Evidence in Medical Malpractice Suits*, 44 U. CHI. L. REV. 398, 405-18 (1977) [hereinafter cited as Comment, *Package Inserts as Evidence*].

34. 21 U.S.C. § 355(d)(1) (1976); Merrill, *supra* note 3, at 8.

35. 21 U.S.C. § 355(d)(5) (1976); Pruzan, *supra* note 5, at 711. The Supreme Court has upheld the FDA's authority to issue regulations. *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609 (1973); *Ciba Corp. v. Weinberger*, 412 U.S. 640 (1973); *Weinberger v. Pharmaceuticals*, 412 U.S. 645 (1973); *USV Pharmaceutical Corp. v. Weinberger*, 412 U.S. 655 (1973).

36. 21 U.S.C. § 355 (1976); Comment, *Package Inserts as Evidence*, *supra* note 33, at 409.

37. 21 U.S.C. § 355(d)(6) (1976).

38. 21 U.S.C. § 355(b) (1976); 21 C.F.R. § 314.1 (1983); Merrill, *supra* note 3, at 8.

39. See 2 S. PEGALIS & H. WACHSMAN, *supra* note 2, at § 9.12.

40. 21 C.F.R. § 201.100 (1983); Averbach, *supra* note 6, at 549.

41. 21 C.F.R. § 201.100(c)(1) (1983).

as part of the NDA,⁴² however, the FDA must approve the scope and accuracy of the information provided in the insert prior to release of the new pharmaceutical.⁴³ Therefore, the final insert is a product of negotiations between the drug manufacturer and the FDA.⁴⁴ "The FDA considers the insert to have a twofold purpose: to alert physicians to the conditions under which the drug is deemed safe and effective; and to limit the claims a manufacturer can make about the drug product."⁴⁵ If after a drug has been approved for marketing, new information is received which indicates adverse reactions, the FDA may withdraw approval or demand that the manufacturer revise the insert.⁴⁶ This continuous duty to update and warn of newly discovered dangers and contraindications requires performance at "the earliest possible time."⁴⁷

Considering the regulatory controls, the physician may justifiably rely on the drug manufacturer to provide adequate information for the safe use of the drug. "[T]he FDA considers the package insert authoritative, [and] it considers that to mean that the insert is medically sound. The FDA wants the physician and patient to know that the package insert is backed by substantial evidence and that they can believe what they read in the insert."⁴⁸

Although the package insert is actually sent with the product to the pharmacist, doctors have access to inserts through the *Physician's Desk Reference* (PDR),⁴⁹ a source which reprints most package inserts.⁵⁰ The PDR is published annually and each licensed physician receives a complimentary copy.⁵¹ Ninety-seven percent of all doctors use the PDR as a reference for the safe use of drugs.⁵²

Indeed, the federal regulations on full disclosure grew, in part, out of the informational needs of doctors.⁵³ Due to the vast number of drugs marketed and the multitude of medical articles

42. 21 U.S.C. § 355(b)(6) (1976); Sagall, *The Drug Package Insert*, 7 TRIAL, Mar.-Apr. 1971, at 59.

43. 21 U.S.C. § 355(d) (1976); Sagall, *supra* note 42, at 59.

44. Comment, *Package Inserts as Evidence*, *supra* note 33, at 410.

45. Hirsh, *supra* note 9, at 145.

46. 21 U.S.C. § 355(e) (1976); Averbach, *supra* note 6, at 550; Comment, *Package Inserts as Evidence*, *supra* note 33, at 412.

47. 21 C.F.R. § 314.8(d) (1983); Comment, *Package Inserts as Evidence*, *supra* note 33, at 412.

48. Hirsh, *supra* note 9, at 148.

49. MEDICAL ECONOMICS, INC., THE PHYSICIAN'S DESK REFERENCE (1983).

50. See Sagall, *supra* note 42, at 60.

51. Comment, *Package Inserts as Evidence*, *supra* note 33, at 398 n.2.

52. *Id.* at 416 n.90. However, physicians consider medical journals a more reliable source of information. *Id.*

53. Hirsh, *supra* note 9, at 144.

written on the use of prescription drugs,⁵⁴ the practitioner simply does not have the time to keep apprised of the developments concerning all drugs.⁵⁵ No single doctor could possibly be proficient in the handling of all prescription drugs.

There are about 12,000 different drugs on the market; none are completely safe and all have potential side effects, some minor and some major. Yet any licensed doctor is free to prescribe any drug in any way, regardless of the extent of his training or how diligently he keeps his knowledge up-to-date.⁵⁶

Clearly, the drug manufacturer's recommendation must be the starting point for determining the proper standard of care required of physicians in the administration of prescription drugs.⁵⁷

There are an increasing number of gross medical errors in administering a drug or where there has been a failure to exercise proper precautions. Drug toxicity is all too common where directions for use are followed to the letter without regard to the individuality of the patient. It is almost inevitable when such instructions are disregarded.⁵⁸

In any case involving the negligence of a physician for prescribing a drug, the preliminary inquiry should be first what the manufacturer recommended regarding the use of the drug; and, then whether the doctor followed that recommendation. A physician's reliance upon the drug manufacturer's recommendations by way of the package insert or the PDR is justified for three reasons: (1) the recommendations must provide complete and accurate information for safe use to enable the manufacturer to avoid civil liability; (2) the manufacturer must comply with the federal regulations to avoid the potential economic burden it could incur if the FDA withdrew approval of the drug for marketing; and (3) doctors out of necessity do, in fact, rely on the package insert and the

54. It is estimated that, the medical profession writes over 200,000 articles on the use of drugs each year. Averbach, *supra* note 6, at 537 n.7.

55. *Id.* at 537.

56. 1 S. PEGALIS & H. WACHSMAN, *supra* note 2, at § 1.9. "[A] medical colleague has suggested that physicians should be licensed like pilots—restricted in the drugs they could prescribe, based on their education, training, and, presumably, competence." Merrill, *supra* note 3, at 111.

57. See, e.g., Dyer v. Best Pharmacal, 118 Ariz. 465, 468, 577 P.2d 1084, 1088 (Ariz. Ct. App. 1978) (doctor's disregard of the manufacturer's express warnings was unforeseeable); Cambell v. Preston, 379 S.W.2d 557, 561 (Mo. 1964) (doctor's alleged negligence was failure to follow the package insert); Baker v. St. Agnes Hosp., 70 A.D.2d 400, 405, 421 N.Y.S.2d 81, 85 (1979) (standards of competent medical practice require that doctors obtain knowledge of the drug from the manufacturer before administering it); Koury v. Follo, 272 N.C. 366, 376, 158 S.E.2d 548, 556-57 (1968) (package insert is evidence of a warning, which the doctor disregards at his peril, and such disregard is relevant on the issue of reasonable care).

58. Averbach, *supra* note 6, at 555; accord S. PEGALIS & H. WACHSMAN, *supra* note 2, at § 9.7.

PDR.⁵⁹

Common sense would seem to indicate that the package insert and the PDR should play significant roles in malpractice litigation. Surprisingly, the courts' traditional question has been whether the package insert or the PDR is admissible into evidence on the issue of the physician's proper standard of care in prescribing drugs.⁶⁰

III. THE PACKAGE INSERT AND THE HEARSAY RULE

Under the hearsay rule, the package insert traditionally received the same treatment as a medical book and, as such, was inadmissible to prove the truth of its contents.⁶¹ The rule barring admission of medical treatises was based on the rationale⁶² that: (1) the author was not under oath when the book was written;⁶³ (2) the author could not be subjected to cross-examination;⁶⁴ (3) medical science changed too rapidly for any book to be trustworthy;⁶⁵ (4) the jury would misunderstand or misapply technical language without the aid of expert testimony;⁶⁶ and (5) the standard of care for physicians is based on the personal experience of other physicians, rather than medical texts.⁶⁷

In contrast, it is Professor Wigmore's view that, due to the trustworthiness of medical treatises and the necessity for their use at trial, medical treatises should be admissible under an exception to the hearsay rule.⁶⁸ Use of the medical treatises as evidence often becomes necessary because of the difficulty of obtaining expert

59. Merrill, *supra* note 3, at 104.

60. *Id.* at 54.

61. See, e.g., Poulin v. Zartman, 542 P.2d 251 (Alaska 1975); Nolan v. Dillon, 261 Md. 516, 276 A.2d 36 (1971); Koury v. Follo, 272 N.C. 366, 158 S.E.2d 548 (1968); Eckleberry v. Kaiser Found. Northern Hosp., 226 Or. 616, 359 P.2d 1090 (1961) (statute which allowed "books of science or art" to be admitted into evidence did not apply to medical books); Webb v. Jorns, 530 S.W.2d 847 (Tex. Civ. App. 1975). See generally 2 S. GARD, JONES ON EVIDENCE § 12:31 (6th ed. 1972); 3 C. KRAMER, MEDICAL MALPRACTICE § 29.06 (1982); Comment, *Substantive Admissibility of Learned Treatises and the Medical Malpractice Plaintiff*, 71 NW. U.L. REV. 678 (1976).

62. 6 J. WIGMORE, EVIDENCE IN TRIALS AT COMMON LAW § 1690 (1976).

63. See, e.g., Poulin v. Zartman, 542 P.2d 251, 267 (Alaska 1975); Koury v. Follo, 272 N.C. 366, 376, 158 S.E.2d 548, 556 (1968).

64. See, e.g., Poulin v. Zartman, 542 P.2d 251, 267 (Alaska 1975); Koury v. Follo, 272 N.C. 366, 376, 158 S.E.2d 548, 556 (1968); Webb v. Jorns, 530 S.W.2d 847, 856 (Tex. Civ. App. 1975). See generally 2 S. PEGALIS & H. WACHSMAN, *supra* note 2, at § 11.8.

65. See, e.g., Poulin v. Zartman, 542 P.2d 251, 267 (Alaska 1975); Koury v. Follo, 272 N.C. 366, 375, 158 S.E.2d 548, 555 (1968); 2 S. GARD, *supra* note 61, at § 12.31.

66. 6 J. WIGMORE, *supra* note 62, at § 1690.

67. See, e.g., Webb v. Jorns, 530 S.W.2d 847, 856 (Tex. Civ. App. 1975); 6 J. WIGMORE, *supra* note 62, at § 1690.

68. 6 J. WIGMORE, *supra* note 62, at §§ 1691-92. See also Tittle v. Hurlbutt, 53 Ha-

witnesses in the typical medical malpractice case.⁶⁹ A medical text is trustworthy because the author did not make the statement with a view toward litigation and obviously could not have been biased toward any of the parties to a lawsuit.⁷⁰ A medical treatise is probably more accurate than the testimony of many expert witnesses.⁷¹ "It must be conceded that those who write with no view to litigation are at least as trustworthy, though unsworn and unexamined, as perhaps the greater portion of those who take the stand for a fee from one of the litigants."⁷² A few jurisdictions have adopted the Wigmore position and do admit medical treatises as evidence of the proper standard of care, as an exception to the hearsay rule.⁷³

waii 526, 534, 497 P.2d 1354, 1359 (1972) (The court recognized the need for wider use of medical texts as evidence.).

69. See, e.g., Poulin v. Zartman, 542 P.2d 251, 267-68 (Alaska 1975); Winkjer v. Herr, 277 N.W.2d 579, 589 (N.D. 1979); Lewandowski v. Preferred Risk Mutual Ins. Co., 33 Wis. 2d 69, 76, 146 N.W.2d 505, 509 (1966). See generally Comment, *Package Inserts as Evidence*, *supra* note 33, at 426; Comment, *supra* note 61, at 680. The Secretary's Commission on Medical Malpractice recommends that organized medicine establish "an official policy encouraging members of their profession to cooperate fully in medical malpractice actions so that justice will be assured for all parties; and the Commission encourages the establishment of pools from which expert witnesses can be drawn." REPORT OF THE SECRETARY'S COMM'N, *supra* note 1, at 37.

70. See, e.g., Poulin v. Zartman, 542 P.2d 251, 267 (Alaska 1975); Julien v. Barker, 75 Idaho 413, 423, 272 P.2d 718, 724 (1954). But see O'Brien v. Angley, 63 Ohio St. 2d 159, 407 N.E.2d 490 (1980) (admission of an article was error because it was written with a view toward litigation and lacked the requisite indicia of objectivity and trustworthiness).

71. Poulin v. Zartman, 542 P.2d 251, 267 (Alaska 1975).

72. 6 J. WIGMORE, *supra* note 62, at § 1692.

73. Alabama: *Murdoch v. Thomas*, 404 So. 2d 580, 585 (Ala. 1981) (party must prove that the treatise was recognized as an authoritative one); *Berry v. Robertson*, 285 Ala. 623, 630-31, 235 So. 2d 657, 663 (1970) (a treatise recognized as trustworthy is admissible); *City of Dothan v. Hardy*, 237 Ala. 603, 607, 188 So. 264, 265 (1939) (medical books ought to be received into evidence); Connecticut: *Cross v. Huttenlocher*, 440 A.2d 952, 955 (1981) (treatise admissible within trial court's discretion if recognized as authoritative and relevant); Kansas: *State v. McDonald*, 222 Kan. 494, 495, 565 P.2d 267, 269 (1977) (statements in treatises, offered to prove the truth of the matter stated therein, exceptions to the hearsay rule and received in evidence); KAN. STAT. ANN. § 60-460(cc) (1976) (treatises admitted according to the Uniform Rules of Evidence); Kentucky: *Heilman v. Synder*, 520 S.W.2d 321, 322 (Ky. 1975) (treatises admitted according to the Uniform Rules of Evidence); Massachusetts: MASS. GEN. LAWS ANN. ch. 233, § 79C (West Supp. 1983-84) (statements in treatise admissible as evidence to prove said facts, if relevant and the writer recognized as an expert); Wisconsin: *Halldin v. Peterson*, 39 Wis. 2d 668, 674, 159 N.W.2d 738, 741 (1968) (plaintiff may establish the standard of care and the doctor's breach thereof by medical texts); *Lewandowski v. Preferred Risk Mutual Ins.*, 33 Wis. 2d 69, 76, 146 N.W.2d 505, 509 (1966) (adopted the view of the Uniform Rules of Evidence, stating: "This is but another example of accepting the scientific process in the search for truth instead of reliance upon the efficacy of an oath as a guaranty of trustworthiness."); WIS. STAT.

Thus, the package insert or the PDR is admissible in those jurisdictions.

Regardless of the admissibility of medical books in general, there is further justification for admitting the PDR or package insert as an exception to the hearsay rule.⁷⁴ The author of the package insert—the manufacturer—must provide accurate and complete information for the safe use of the drug both to avoid potential civil liability⁷⁵ and to comply with federal law.⁷⁶ This duty is a continuing one; unlike the author of a medical treatise, the manufacturer must provide the most current information to the practitioner.⁷⁷ While medical books may become obsolete, the package insert must be kept current. In addition, physicians do rely heavily on the PDR or package inserts in the practice of medicine.⁷⁸ The supervisory role of the FDA ensures the trustworthiness of the drug manufacturer's recommendation and arguably serves as a substitute for cross-examination of the manufacturer.⁷⁹ Although the manufacturer is not technically under oath when he writes the package insert, the federal regulations serve the function of an oath, ensuring the truthfulness and veracity of the NDA and the package insert.⁸⁰ Clearly, the package insert and the PDR are more trustworthy than most medical books and should be admitted into evidence as an exception to the hearsay rule, to prove the standard of care, even in a jurisdiction which generally does not admit medical treatises as evidence.

The recent trend is to follow this view by allowing the package insert into evidence on some issues. Medical treatises have always been admissible to impeach the credibility of an expert witness on cross-examination.⁸¹ The Federal Rules of Evidence expanded this view somewhat, and allow admission of medical treatises and package inserts:

§ 908.03(18) (1975) (Uniform Rules). *See also* UNIF. R. EVID. 63(31) (1953) (A medical treatise is not hearsay, when offered to prove the truth of the matter stated therein, if the judge takes judicial notice, or an expert testifies, that the source is a reliable authority.).

74. *See* Comment, *Package Inserts as Evidence*, *supra* note 33, at 426-30.

75. *See supra* notes 15-29 and accompanying text. *See also* Julien v. Barker, 75 Idaho 413, 423, 272 P.2d 718, 724 (1954).

76. *See supra* notes 40-48 and accompanying text.

77. *See supra* notes 27-29 & 46-47 and accompanying text.

78. *See supra* notes 50-56 and accompanying text.

79. *See* Comment, *Package Inserts as Evidence*, *supra* note 33, at 422-26.

80. 21 U.S.C. § 352(n) (Supp. II 1978); 21 C.F.R. §§ 202.1(e)(3), 314.9, 314.110(4), 314.111, 314.115(b)(1), (b)(3)-(4) (1983).

81. *See, e.g.*, Poulin v. Zartman, 542 P.2d 251, 267-68 (Alaska 1975); Stanek v. Bergeon, 89 Mich. App. 283, 286, 279 N.W.2d 296, 297 (1979); Dinner v. Thorp, 54 Wash. 2d 90, 93, 338 P.2d 137, 141-42 (1959). *See generally* 2 S. GARD, *supra* note 61, at § 12:32; 6 J. WIGMORE, *supra* note 62, at § 1700.

[T]o the extent called to the attention of an expert witness upon cross-examination or relied upon by him in direct examination, statements contained in published treatises . . . or pamphlets on a subject of . . . medicine . . . established as a reliable authority by the testimony or . . . by judicial notice. If admitted, the statements may be read into evidence but may not be received as exhibits.⁸²

Although these two rules would seem to provide for broad admissibility of package inserts, both the Federal Rules and the common law rule, which allows the use of the manufacturer's recommendation for impeachment purposes, may be circumvented if an expert refuses to concede that the package insert is valid "authority."⁸³ "On cross-examination without the admission by the medical expert . . . that he honored and accepted the recommendations of the manufacturer as 'authority' . . . the manufacturer's recommendation could never qualify as an exception to the general rule which excludes hearsay"⁸⁴ Furthermore, both rules downplay the significance of the drug manufacturer's recommendation as the starting point for good medical treatment in prescribing or administering drugs.⁸⁵

Some courts have refused to acknowledge that a package insert should be introduced to show the proper standard of care,⁸⁶ yet have admitted the insert to show that the physician knew or should have known of its contents.⁸⁷ In *Koury v. Follo*,⁸⁸ the defendant administered injections of Strep-Combiotic to plaintiff's

82. FED. R. EVID. § 803(18) (1975). For a listing of the states that have adopted the federal rules, see 2 S. PEGALIS & H. WACHSMAN, *supra* note 2, at § 11.18 n.19; 6 J. WIGMORE, *supra* note 62, § 1693 n.6 (Supp. 1983). For a general discussion of the use of medical treatises under the federal rules, see Comment, *supra* note 61.

83. See, e.g., Webb v. Jorns, 530 S.W.2d 847, 856-57 (Tex. Civ. App. 1975).

84. *Id.* Maggipinto v. Reichman, 481 F. Supp. 547 (E.D. Pa.), *remanded*, 607 F.2d 621 (3d Cir. 1979). The Maggipinto case was remanded to determine whether the trial court granted the defendant's motion to dismiss because the plaintiff had failed to introduce expert testimony to support her claim of dental malpractice. The plaintiff had used two medical treatises to impeach the testimony of the defendant dentist; however, the defendant refused to acknowledge them as reliable authority. Because the treatises were never shown to be "reliable sources" under the federal rules, they were used solely for impeachment purposes, and not as substantive evidence of the proper standard of care. The motion to dismiss was proper for lack of substantive evidence on the negligence claim. The court noted that "the Federal Rules of Evidence clearly placed the burden of showing that the treatises fit within Rule 803 (18) squarely on the plaintiff . . . to establish to the satisfaction of the Court that the treatise is 'reliable authority'" *Id.* at 550.

85. Comment, *Evidentiary Aspects of Manufacturer Recommendations in Establishing Physicians' Standard of Care*, 31 ARK. L. REV. 477, 482 (1977).

86. See *supra* note 48-60 and accompanying text.

87. See, e.g., Sanzari v. Rosenfeld, 34 N.J. 128, 139-40, 167 A.2d 625, 631 (1961); Koury v. Follo, 272 N.C. 366, 376, 158 S.E.2d 548, 556 (1968).

88. 272 N.C. 366, 158 S.E.2d 548 (1968).

infant daughter despite the manufacturer's recommendation that the drug was "not for pediatric use."⁸⁹ The drug caused the daughter to become deaf.⁹⁰ The court acknowledged that the recommendation was inadmissible hearsay as offered to prove the truth of the statement "not for pediatric use."⁹¹ However, it was admissible to show that the defendant doctor should have been aware of the danger.⁹² This holding begs the question; if the defendant should know of the danger why is he not required to act in accordance with such knowledge? In *Koury*, this rationale would have established the standard that the defendant should not prescribe the drug for infants, as recommended by the manufacturer.

When the recommendation is introduced as proof of the doctor's knowledge of its contents, the plaintiff still must introduce expert testimony to establish both the standard of care the defendant doctor should have used and the fact that he departed from that standard. For example, in *Sharpe v. Pugh*,⁹³ the defendant doctor prescribed the drug chloromycetin three times over a seven-month period to two-year old Brenda for viral infections.⁹⁴ The package insert stated that aplastic anemia could occur after the administration of chloromycetin, that the drug should not be used where other less dangerous drugs would be effective, and that it was "essential that adequate blood studies be made during treatment."⁹⁵ Brenda died from aplastic anemia.⁹⁶ No blood tests were adminis-

89. *Id.* at 376, 158 S.E.2d at 550.

90. *Id.*

91. *Id.* at 382, 158 S.E.2d at 556.

92. *Id.* ("It is evidence of a warning which the physician disregards at his peril.") In *Sanzari v. Rosenfeld*, 34 N.J. 128, 167 A.2d 625 (1961), the defendant dentist injected an anesthetic solution containing Epinephrine, preparing to fill the patient's tooth. The drug manufacturer's recommendation provided that Epinephrine was contraindicated if the patient suffered from high blood pressure because the drug would raise the patient's blood pressure and could cause a stroke in hypertensive patients. The patient had high blood pressure and suffered a stroke from the injection. *Id.* at 132, 167 A.2d at 627. The recommendation was inadmissible on the standard of care required of the dentist. *Id.* at 139, 167 A.2d at 631. However, the package insert was evidence that the dentist had notice that Epinephrine might be harmful to hypertensive patients. *Id.*

93. 21 N.C. App. 110, 203 S.E.2d 330, *aff'd*, 286 N.C. 209, 209 S.E.2d 456 (1974) (The Supreme Court was equally divided. Under North Carolina court rules, when this occurs, the decision of the Court of Appeals must be affirmed. Any legal issues so decided do not become precedent for future cases.).

94. *Sharpe v. Pugh*, 21 N.C. App. 110, 111, 203 S.E.2d 330, 331 (1974). Chloromycetin was to be used for bacterial infections only, not viral infections. *Id.* at 115, 203 S.E.2d at 333. In 1973, 95 percent of patients with a common cold received prescriptions, one-half of which were for antibiotics, which cannot kill cold viruses. 1 S. PEGALIS & H. WACHSMAN, *supra* note 2, at § 1.9.

95. *Sharpe v. Pugh*, 21 N.C. App. 110, 113, 203 S.E.2d 330, 332-33 (1974).

96. *Id.* at 112, 203 S.E.2d at 332. Aplastic anemia is caused by deficient red cell

tered until the seventh month of treatment.⁹⁷ Although the insert was admissible as to whether the doctor knew of its contents,⁹⁸ the directed verdict against the plaintiff was upheld because there was no expert testimony to establish the proper standard of care.⁹⁹

Assuming, *arguendo*, that [the package inserts] were admissible to show that defendant knew, or should have known, of the dangerous propensities of chloromycetin, we are of the opinion that there was a complete lack of evidence to establish the standard of care which defendant was required to adhere to . . .¹⁰⁰

In light of the drug manufacturer's specific recommendation, the plaintiff should have been allowed, at least, to establish a *prima facie* case on remand, which would have forced the defendant to explain why he prescribed the powerful drug chloromycetin in the first place and why he did not administer blood tests as recommended. Under the circumstances of *Sharpe v. Pugh*, the requirement of expert testimony to show the standard of care was an unnecessary burden, which prevented a decision on the merits.

Many courts have allowed the drug manufacturer's recommendation into evidence to demonstrate the physician's proper standard of care in the administration or prescription of a drug,¹⁰¹ as an exception to the rule against hearsay evidence.¹⁰² These courts do not consider the inserts determinative of the standard of care, but rather evidence of that standard.

[The package insert] is not conclusive evidence of standard or accepted practice in the use of the drug by physicians and surgeons, nor that a departure from such directions is negligent. But it is *prima facie* proof of a proper method of use, given by the maker, which must be presumed qualified to give directions for its use and warnings of any danger inherent therein.¹⁰³

production due to disorders of bone marrow. *TABER'S CYCLOPEDIA MEDICAL DICTIONARY* A-108 (14th ed. 1981).

97. *Sharpe v. Pugh*, 21 N.C. App. 110, 111, 203 S.E.2d 330, 331 (1974).

98. *Id.* at 114, 203 S.E.2d at 333.

99. *Id.* at 115, 203 S.E.2d at 334. *Accord* *Maggipinto v. Reichman*, 481 F. Supp. 547 (E.D. Pa.), *remanded*, 607 F.2d 621 (3d Cir. 1979).

100. *Sharpe v. Pugh*, 21 N.C. App. 110, 115, 203 S.E.2d 330, 333 (1974).

101. *Chrestman v. Kendall*, 247 Ark. 802, 448 S.W.2d 22 (1969); *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 317 P.2d 170 (Cal. Dist. Ct. App. 1957); *Julien v. Barker*, 75 Idaho 413, 272 P.2d 718 (1954); *Nolan v. Dillon*, 261 Md. 516, 276 A.2d 36 (1971); *Marchese v. Monaco*, 52 N.J. Super. 474, 145 A.2d 809 (N.J. Super. Ct. Div. 1958), *cert. denied*, 28 N.J. 565, 147 A.2d 609 (1959); *Crouch v. Most*, 78 N.M. 406, 432 P.2d 250 (1967); *Wasem v. Laskowski*, 274 N.W.2d 219 (N.D. 1979); *Reed v. Church*, 175 Va. 284, 8 S.E.2d 285 (1940). *See also* *Boucheron v. Tilley*, 87 A.D.2d 983, 450 N.Y.S.2d 110 (1982) (The court indicated that the package insert would have been admissible if proper foundational testimony had been given at trial.).

102. *See, e.g., Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 317 P.2d 170 (Cal. Dist. Ct. App. 1957); *Julien v. Barker*, 75 Idaho 413, 272 P.2d 718 (1954).

103. *Julien v. Barker*, 75 Idaho 413, 423, 272 P.2d 718, 724 (1954).

Certainly, this exception is a step in the right direction; however, there are still two obstacles that prevent a plaintiff from using the package insert effectively in a medical malpractice case. First, the plaintiff must still introduce expert witnesses on the proper standard of care,¹⁰⁴ even if the expert only testifies that the insert was the standard under the circumstances of the case.¹⁰⁵

Thus, while [the package insert is] admissible, it cannot establish as a matter of law the standard of care required of a physician in the use of the drug. It may be considered by the jury along with the other evidence in the case to determine whether the particular physician met the standard of care required of him. The court's instruction on the subject should have been limited to this effect.¹⁰⁶

Second, the defendant doctor can circumvent the mandate of the package insert by offering expert testimony that doctors do not rely on the manufacturer's recommendation as a determination of proper medical treatment.¹⁰⁷ In some instances, the doctor may be

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104. See, e.g., *Berry v. Robertson*, 285 Ala. 623, 235 So. 2d 657 (1970); *Chrestman v. Kendall*, 247 Ark. 802, 448 S.W.2d 22 (1969); *Crouch v. Most*, 78 N.M. 406, 432 P.2d 250 (1967). In *Crouch v. Most*, Crouch had received a rattlesnake bite on his fingers. Dr. Most injected Antivenin into the finger despite the clear prohibition in the package insert: "[d]o not inject the serum into a finger or toe." *Id.* at 407, 432 P.2d at 251. The injection allegedly resulted in the amputation of two of Crouch's fingers. *Id.* Despite the direct warning by the manufacturer and the defendant's acknowledgment that the warning was proof of a proper method of use, the judgment in favor of Dr. Most was upheld because the plaintiff failed to produce sufficient expert testimony on the standard of care. *Id.* at 407-08, 432 P.2d at 254.
 105. See, e.g., *Nolan v. Dillon*, 261 Md. 516, 534-35, 276 A.2d 36, 40, 46 (1971) (expert testified that the package insert represented the standard of care followed by physicians); *Reed v. Church*, 175 Va. 284, 297, 8 S.E.2d 285, 290 (1940) (defendant doctor testified that he followed the package insert's instructions; therefore, he was not prejudiced by the insert's introduction into evidence).
 106. *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 577, 317 P.2d 170, 180 (Cal. Dist. Ct. App. 1957).
 107. In *Haynes v. Baton Rouge Hosp.*, 298 So. 2d 149 (La. Ct. App. 1974), the court held that there was a failure to demonstrate that the defendant doctor deviated from the standard of care due his patient by prescribing the antibiotic Keflex, notwithstanding the drug company's literature warning that Keflex had not been demonstrated to be effective against most forms of bacterial infections. *Id.* at 155. The defendant doctor testified "you certainly don't practice your medicine off a drug flyer." *Id.* at 153. The defendant doctor was allowed throughout his testimony to downplay any warnings contained in a drug manufacturer's recommendation. *Id.* In *Brune v. Belinkoff*, 354 Mass. 102, 235 N.E.2d 793 (1968), the plaintiff was administered eight milligrams of pontocaine, a spinal anesthetic, instead of two to five milligrams, the dosage recommended by the drug manufacturer. *Id.* at 103, 235 N.E.2d at 798. The court upheld the trial court's refusal to instruct the jury that failure to follow the manufacturer's instruction was evidence of negligence. The court reasoned that it was "no more than a recommendation, and there was a difference of opinion among the anesthesiologists as to whether the failure to follow it was improper practice." *Id.* at 103, 235 N.E.2d at 799. "[The plaintiff]

justified in disregarding a package insert. However, it is simply unacceptable to allow the manufacturer's recommendation to be ignored on the rationale that it is customarily disregarded by physicians, in light of the fact that the usage and dosage instructions must be supported by sufficient scientific proof in order to receive FDA approval.¹⁰⁸ In these cases, the doctor should be called upon to explain why he disregarded the express recommendation of the drug manufacturer; he should not be allowed to hide behind the shield of the expert testimony requirement or the customary practice rule.

IV. USE OF THE PACKAGE INSERT TO ESTABLISH THE STANDARD OF CARE

Once the package insert is admitted under an exception to the hearsay rule, it remains to be determined under what circumstances the drug manufacturer's recommendation should establish the physician's standard of care in the administration and prescription of drugs. Traditionally, the recommendation has been allowed to set the standard only if an expert testifies, or the defendant doctor admits, that it should have been followed under the facts of a particular case.¹⁰⁹ However, a few courts have allowed the package insert to establish the plaintiff's *prima facie* case of negligence, without supporting expert testimony.

In the landmark decision of *Mulder v. Parke Davis & Co.*,¹¹⁰ the Supreme Court of Minnesota held:

Where a drug manufacturer recommends to the medical profession (1) the conditions under which its drug should be prescribed; (2) the disorders it is designed to relieve; (3) the precautionary measures which should be observed; and (4) warns of the dangers which are inherent in its use, a doctor's deviation from such recommendations is *prima facie* evidence of negligence if there is competent medical testimony that his patient's injury or death resulted from the doctor's failure to adhere to the recommendations. Under such circumstances, it is incumbent on the doctor to disclose his reasons for departing from the procedures recommended by the manufacturer. Although it will ordinarily be a jury

frequently will be defeated by well-established professional customs that courts refuse to scrutinize for reasonableness." Merrill, *supra* note 3, at 67.

108. See generally Comment, *Package Inserts as Evidence*, *supra* note 33, at 432-33, 443, 449. Ninety-seven percent of all doctors do, in fact, rely heavily on the drug manufacturer's recommendation. See *supra* note 52.

109. Chrestman v. Kendall, 247 Ark. 802, 809, 448 S.W.2d 22, 26 (1969); Nolan v. Dillon, 261 Md. 516, 534-35, 540, 276 A.2d 36, 40, 46 (1971); Holloway v. Hawver, 22 Md. App. 303, 319, 322 A.2d 890, 898 (Md. Ct. Spec. App. 1974); Marchese v. Monaco, 52 N.J. Super. 474, 487, 145 A.2d 809, 816 (N.J. Super. Ct. App. Div. 1958), *cert. denied*, 28 N.J. 565, 147 A.2d 609 (1959); Holland v. Stacy, 496 P.2d 1180, 1183 (Okla. 1972); Webb v. Jorns, 530 S.W.2d 847, 856, 858 (Tex. Civ. App. 1975); Reed v. Church, 175 Va. 284, 298, 8 S.E.2d 285, 290 (1970).

110. 288 Minn. 332, 181 N.W.2d 882 (1970).

question whether the doctor has justified or excused his deviation, there may be situations where as a matter of law the explanation exonerates him unless rebutted by other competent medical testimony.¹¹¹

The court further explained the *Mulder* decision in *Lhotka v. Larson*:¹¹² "[u]nderlying *Mulder* is the self-evident premise that deviation from a manufacturer's recommendations constitutes prima facie evidence of negligence only when the conduct complained of deviates from standards which are clear and explicit."¹¹³ The courts of South Dakota¹¹⁴ and Illinois¹¹⁵ have also adopted the position that deviation from the clear and explicit recommendations of the drug manufacturer establishes the plaintiff's *prima facie* case.

It is an inherent weakness of *Mulder* and its progeny that virtually all prescription drugs and their accompanying package inserts will meet the four-prong test to bring the *prima facie* evidence rule into operation.¹¹⁶ All drug manufacturer's recommendations must contain precisely that information to comply with FDA requirements.¹¹⁷ From that standpoint, the *Mulder* test is overbroad. However, *Lhotka* limited the test by adding the further requirement that the recommendation establish a clear and explicit standard.¹¹⁸ A court should consider the clear and explicit requirement satisfied when a lay jury could conclude from the recommendation and the facts of the case that the doctor was negligent. A standard of care is clear and explicit when the facts of the case and the recommendation are such that the jury needs no further expert testimony to assist them; the determination falls within the jury's common knowledge.

In medical malpractice cases, expert testimony is needed unless *res ipsa loquitur* or the common knowledge rule applies.¹¹⁹

111. *Id.* at 339-40, 181 N.W.2d 882, 887-88 (upon petition for rehearing). See also *Cornfeldt v. Togen*, 262 N.W.2d 684, 703 (Minn. 1977).

112. 307 Minn. 121, 238 N.W.2d 870 (1976) (case discussed *infra* notes 137-42 and accompanying text).

113. *Id.* at 127 n.14, 238 N.W.2d at 874 n.14 (1976).

114. *Mueller v. Mueller*, 88 S.D. 446, 221 N.W.2d 39 (1974) (facts discussed *infra* note 136).

115. *Ohligschlager v. Proctor Community Hosp.*, 55 Ill. 2d 411, 418, 303 N.E.2d 392, 396 (1973) (facts discussed *infra* note 136). *Callan v. Nordland*, 114 Ill. App. 3d 196, 448 N.E.2d 651 (1983) (*Ohligschlager* applied, and manufacturer's recommendation for the drug the pharmacist actually supplied to the patient was admissible, even though the doctor prescribed the drug by a generic name); *Spilotro v. Hugi*, 93 Ill. App. 3d 837, 417 N.E.2d 1066 (1981) (recognized *Ohligschlager* could be applied in a negligence action against a veterinarian); *Conrad v. Christ Community Hosp.*, 77 Ill. App. 3d 337, 395 N.E.2d 1158 (1979).

116. *Merrill*, *supra* note 3, at 64-65.

117. See *supra* notes 40-41 and accompanying text.

118. *Lhotka v. Larson*, 307 Minn. 121, 127 n.14, 238 N.W.2d 870, 874 n.14 (1976).

119. See generally Comment, *Malpractice Actions Without Expert Medical Testi-*

The common knowledge rule applies when the physician's alleged act of negligence falls within the general knowledge of a layperson and, therefore, the standard of care and breach thereof need not be established by expert testimony.¹²⁰ Although the common knowledge rule generally is not applied in cases involving negligence in the use of prescription drugs,¹²¹ it should be applied in combination with the drug manufacturer's recommendations to allow the jury to determine negligence.¹²² The common knowledge rule is a further limitation on the *Mulder* decision. The physician's deviation from the package insert is *prima facie* evidence of negligence only if the common knowledge rule is also applied, otherwise, expert testimony would be required.

The North Dakota Supreme Court apparently adopts this approach. In *Winkjer v. Herr*,¹²³ the court stated:

Although plaintiff may be correct in his contention that the published warnings and recommendations, *combined with the common knowledge doctrine*, may have been sufficient to present a *prima facie* case of negligence in the prescription of phospholine iodide for a diagnosis of ocular hypertension, those are not the facts of this case. Rather, there was a prescription for a condition diagnosed as glaucoma.¹²⁴

Even though few courts have specifically applied the common knowledge rule,¹²⁵ the facts of most of the prescription negligence cases support its application.

In *Mulder*, Dr. Mork prescribed chloromycetin for an ear infection on four occasions to Mrs. Mulder.¹²⁶ The manufacturer

mony, 20 CLEV. ST. L. REV. 43 (1971); Note, *Evidence: Obvious Malpractice—Expert Testimony Not Required*, 13 WASHBURN L.J. 238 (1974).

120. See generally Dahlquist, *Common Knowledge in Medical Malpractice Litigation: A Diagnosis and Prescription*, 14 PAC. L.J. 133 (1983).

121. See, e.g., Wasem v. Laskowski, 274 N.W.2d 219, 224-25 (N.D. 1979); Hundemer v. Sisters of Charity of Cincinnati, Inc., 22 Ohio App. 2d 119, 124, 258 N.E.2d 611, 615 (1969). See generally Merrill, *supra* note 3, at 93.

122. Comment, *supra* note 85, at 481-82. See generally Comment, *Package Inserts as Evidence*, *supra* note 33, at 450.

123. 277 N.W.2d 579 (N.D. 1979). The *Winkjer* decision was decided three months after Wasem v. Laskowski, 274 N.W.2d 219 (N.D. 1979), wherein the court rejected a proposed jury instruction which was based on the *Mulder prima facie* evidence rule; the court disapproved of the words "prima facie" as too technical for the jury to understand. *Id.* at 222-23.

124. *Winkjer v. Herr*, 277 N.W.2d 579, 585 (N.D. 1979) (emphasis added).

125. In *Sanzari v. Rosenfeld*, 34 N.J. 128, 167 A.2d 625 (1961), the Supreme Court of New Jersey held that the "doctrine of common knowledge combined with the manufacturer's brochure, admitted into evidence, was sufficient to avoid a dismissal." *Id.* at 143, 167 A.2d at 633. The insert put the doctor on notice of the drug's risk to hypertensive patients, and it was within the jurors' common knowledge that the doctor should find out whether a patient suffered high blood pressure before administering the drug. *Id.* For a further description of the case, see *supra* note 92.

126. *Mulder v. Parke Davis & Co.*, 288 Minn. 332, 334, 181 N.W.2d 882, 884 (1970).

warned that the drug should only be used for serious infections, and that it should not be used if less dangerous drugs would be effective.¹²⁷ Additionally, the package insert warned that serious or fatal blood disorders (aplastic anemia) could result.¹²⁸ Mrs. Mulder died from aplastic anemia.¹²⁹ A lay juror's knowledge and the manufacturer's express warnings, should require the defendant to explain why he prescribed chloromycetin for an ear infection. Dr. Mork testified he was aware of the warning, but "chose not to be governed by it."¹³⁰ It was implicit in the court's ruling, reversing the directed verdict in favor of Dr. Mork, that the lay jury could properly find Dr. Mork negligent without the assistance of expert testimony,¹³¹ based on its own knowledge and the package insert.

Another case which illustrates that the facts must fall within "common knowledge" before the package insert can establish the standard of care is *Marchese v. Monaco*.¹³² Dr. Monaco prescribed mycifradin to Mr. Marchese, who had impaired kidney functions.¹³³ The drug manufacturer warned that "[u]nder such conditions the benefits that may be derived . . . should be weighed against the possible developments of deafness."¹³⁴ Mr. Marchese received numerous injections and, as a result, was rendered totally deaf.¹³⁵ Without an explanation from Dr. Monaco as to why he had disregarded an express warning, the jury should have been able to conclude, without the aid of expert testimony, that the drug was improperly prescribed.¹³⁶

127. *Id.* at 333-34, 181 N.W.2d 882, 884-85.

128. *Id.* For another case dealing with chloromycetin, see *Sharpe v. Pugh*, 21 N.C. App. 110, 203 S.E.2d 330 (1974) (discussed *supra* notes 93-100 and accompanying text).

129. *Mulder v. Park Davis & Co.*, 288 Minn. 332, 334, 181 N.W.2d 882, 884 (1970).

130. *Id.* at 335, 181 N.W.2d at 885.

131. The court noted that the expert witnesses produced by the plaintiff were not in active practice and emphasized physicians' reluctance to testify against one another as the cause of the plaintiff's difficulty in obtaining qualified experts. *Id.* at 335, 181 N.W.2d at 885-86.

132. 52 N.J. Super. 474, 145 A.2d 809 (N.J. Super. Ct. App. Div. 1958), *cert. denied*, 28 N.J. 565, 147 A.2d 609 (1959).

133. *Id.* at 484, 145 A.2d at 814.

134. *Id.* at 480, 145 A.2d at 813.

135. *Id.* at 485, 145 A.2d at 811.

136. There was, in fact, expert testimony that Dr. Monaco should have used a less dangerous drug because Mr. Marchese's condition was not an "emergency." *Id.* at 481, 484, 145 A.2d at 813, 816. The other cases that rely heavily on package inserts to establish the standard of care support the theory that the facts must fall within the jury's common knowledge. See *Ohligschlager v. Proctor Community Hosp.*, 55 Ill. 2d 411, 303 N.E.2d 392 (1973) (The doctor ordered Sparine concentrations of 50 mg. and 75 mg. intravenously despite the manufacturer's warning that Sparine, when used intravenously, should be used in a concentration no greater than 25 mg. The Sparine infiltrated the tissue of

Many cases will require expert testimony to assist the jury because the jury simply could not understand the drug manufacturer's recommendation. In *Lhotka v. Larson*,¹³⁷ the court held that the *Mulder* test was inapplicable because the recommendation was not "clear and explicit."¹³⁸ The manufacturer had warned that Seconal (a sedative) should not be injected during a premature delivery¹³⁹ and that the dosage should be reduced by 50 percent if administered with Phenergan (an obstetrical sedative).¹⁴⁰ In *Lhotka*, however, Seconal was administered orally, rather than by injection, and was administered three hours before, rather than with, Phenergan.¹⁴¹ A lay jury's common knowledge is not so sophisticated that it would comprehend the difference between administering a drug orally or by injection, and the speed by which a drug dissipates. In such a case, the drug manufacturer's recommendation should not be sufficient to establish a *prima facie* case and the plaintiff should be required to produce expert testimony to explain the proper usage of the drug and whether the doctor's usage was improper.¹⁴²

plaintiff's arm and, as a result, plaintiff had to undergo skin grafts.); *Nolan v. Dillon*, 261 Md. 516, 276 A.2d 36 (1971) (Dr. Nolan injected 50 mg. of Sparine intravenously. The ampule was clearly marked for "intramuscular use only." The package insert stated that intravenously, the concentration should be no more than 25 mg. Immediately after the injection, Mrs. Dillon's hand became discolored and it became necessary to amputate two fingers.); *Sanzari v. Rosenfeld*, 34 N.J. 128, 167 A.2d 625 (1960) (case described *supra* notes 92, 125); *Crouch v. Most*, 78 N.M. 406, 432 P.2d 250 (1967) (case described *supra* note 104); *Koury v. Follo*, 272 N.C. 366, 158 S.E.2d 548 (1968) (case discussed *supra* notes 88-92 and in accompanying text); *Sharpe v. Pugh*, 21 N.C. App. 110, 203 S.E.2d 330 (1974), *aff'd*, 286 N.C. 209, 209 S.E.2d 456 (1974) (case discussed *supra* notes 93-100 and in accompanying text); *Mueller v. Mueller*, 88 S.D. 446, 221 N.W.2d 39 (1974) (Despite the manufacturer's express warnings, Dr. Mueller administered cortisone to the plaintiff over a seven-year period. The excessive and prolonged use of cortisone led to the deterioration of plaintiff's bone structure and the eventual collapse of her right hip.).

137. 307 Minn. 121, 238 N.W.2d 870 (1976).

138. *Id.* at 127, 238 N.W.2d at 874-75.

139. *Id.* at 126, 238 N.W.2d at 874.

140. *Id.* The drugs administered to the mother allegedly crossed the placental barrier and caused severe narcotic-induced respiratory depression. *Id.* at 125, 238 N.W.2d at 873. The child's condition was described as severe mental retardation with spastic quadraparesis and cerebral palsy. *Id.* at 124, 238 N.W.2d at 873.

141. *Id.* at 126, 238 N.W.2d at 874.

142. For other cases dealing with drug manufacturers' recommendations in which the court should require expert testimony because the facts do not fall within the jury's common knowledge, see *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 317 P.2d 170 (Cal. Dist. Ct. App. 1957) (The manufacturer of a dye (Urokon) used for translumbar aortographies, stated that aortography should not be repeated within 24 hours. The defendant testified that the manufacturer's recommendation advised against only a second

A rule which would allow the plaintiff to establish a *prima facie* case of negligence against a physician who deviates from the express instructions or warnings of the manufacturer, as long as the case fell within the common knowledge rule, would not necessarily impose liability. There are still two barriers to recovery. First, the plaintiff must still prove causation; that the physician's improper use of the drug caused the plaintiff's injuries.¹⁴³ Second, the doctor can avoid liability by providing a reason for his departure from the directions. For example, in *Haynes v. Baton Rouge General Hospital*,¹⁴⁴ Mrs. Haynes had undergone surgery for a fractured hip.¹⁴⁵ After surgery, Dr. Stander prescribed Keflex, an antibiotic, for Mrs. Haynes' bacterial infection.¹⁴⁶ The package insert provided that Keflex was not effective against most strains of bacteria.¹⁴⁷ The improper choice of medication allegedly prolonged Mrs. Haynes' recovery. Dr. Stander deviated from the express recommendations and the facts fall within the jury's common knowledge, therefore, Mrs. Haynes should be allowed, under the theory espoused, to establish her *prima facie* case without the aid of expert testimony. Under this analysis it would then be incumbent upon Dr. Stander to disclose why he departed from the warning. Although Keflex was not effective against most bacteria, Dr. Stander had tested Keflex against the particular strain of bacteria that had infected Mrs. Haynes and the laboratory reports showed that Keflex was effective in this case.¹⁴⁸ Dr. Stander justified his depar-

insertion of the needle, not two administrations with the needle left in place within the patient. Although the manufacturer stated 10 to 15 cc. of Urokon was adequate, 50 cc. was recommended in another procedure. Expert testimony was, therefore, required to establish that the defendant's use of 50 cc. in a total of two injections was improper.); *Holland v. Stacy*, 496 P.2d 1180 (Okla. 1972) (Plaintiff was hospitalized with gangrenous toes and the defendant administered Roniacol, a drug that should not be used if a patient has high blood pressure. The plaintiff had a cerebral vascular lesion of thrombosis type. The plaintiff became totally blind after taking the Roniacol. Recovery was properly denied because there was no expert testimony that the plaintiff's disease was covered by the manufacturer's warning and that possibility was not within the jury's common knowledge.).

143. See, e.g., *Lhotka v. Larson*, 307 Minn. 121, 238 N.W.2d 870 (1976) (There were six possible causes of the child's injuries in addition to the doctor's alleged negligence. Recovery was denied.); *Crouch v. Most*, 78 N.M. 406, 432 P.2d 250 (1967) (For a description of the facts, see *supra* note 104. Recovery was denied because either the rattlesnake bite or the injection could have caused the tissue to die.); *Reed v. Church*, 175 Va. 284, 8 S.E.2d 285 (1970) (Plaintiff's condition, incurable syphilis, could have caused the plaintiff's blindness as well as the medication.).

144. 298 So. 2d 149 (La. Ct. App. 1974).

145. *Id.* at 151.

146. *Id.*

147. *Id.* at 152.

148. *Id.* at 152-55.

ture and the "explanation exonerate[d] him unless rebutted by other competent medical testimony."¹⁴⁹

This approach does shift the burden of explanation to the defendant. However, shifting the burden and requiring the defendant to exonerate himself is consistent with the current trend in tort law. In many areas, the courts impose the burden of exoneration upon the defendant to avoid injustice or to assist the plaintiff with problems of proof.¹⁵⁰ The suggested approach would also require the defendant to explain his actions and prevent him from hiding behind the customary practice rule. "A physician's conformity to the custom of his local colleagues should be no defense in drug cases; the issue should be whether the physician departed from sensible pharmacology in his choice or administration of the drug."¹⁵¹

In a few cases outside the prescription drug area, the courts have held that a physician may be liable for malpractice even when he complies with the custom of his profession.¹⁵² These holdings are justified by the rationale that some practices may be so negligent that a jury need not rely on expert testimony that the practice deviates from customary practice; the misconduct falls within the common knowledge rule.¹⁵³ Thus, customary practice is

149. *Mulder v. Parke Davis & Co.*, 288 Minn. 332, 340, 181 N.W.2d 882, 887-88 (1970).

150. *See, e.g.*, *Sindell v. Abbott Lab.*, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132 (1980), *cert. denied*, 449 U.S. 912 (1980); *Barker v. Lull Engineering Co., Inc.*, 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225 (1978); *Haft v. Lone Palm Hotel*, 3 Cal. 3d 756, 478 P.2d 465, 91 Cal. Rptr. 745 (1970); *Summers v. Tice*, 33 Cal. 2d 80, 199 P.2d 1 (1948); *Ybarra v. Spangard*, 25 Cal. 2d 486, 154 P.2d 687 (1944); *Anderson v. Somberg*, 67 N.J. 291, 338 A.2d 1, *cert. denied*, 423 U.S. 929 (1975); *Fosgate v. Corona*, 66 N.J. 268, 330 A.2d 355 (1974).

151. *Merrill*, *supra* note 3, at 111.

152. *See, e.g.*, *Darling v. Charleston Community Memorial Hosp.*, 33 Ill. 2d 326, 211 N.E.2d 253 (1965); *Morgan v. Sheppard*, 91 Ohio App. 579, 188 N.E.2d 808 (1963); *Helling v. Carey*, 83 Wash. 2d 514, 519 P.2d 981 (1974).

153. In the landmark decision of *Helling v. Carey*, 83 Wash. 2d 514, 519 P.2d 981 (1974), the plaintiff, 32 years of age, consulted the defendant for five years for visual problems. In 1968, it was discovered that she had glaucoma and plaintiff had lost her peripheral vision. The defendant had failed to give the plaintiff the pressure test for glaucoma because it was not the custom of the profession to administer the tests for patients under 40 years of age. Accordingly, the trial court entered a judgment for the defendant. The Washington Supreme Court held that "reasonable prudence" required the giving of the pressure test, regardless of custom, because the test was simple, inexpensive, harmless, and conclusive on the presence of glaucoma. Only one out of 25,000 people in plaintiff's age group had glaucoma. The court quoted with approval T.J. Hooper, 60 F.2d 737, 740 (2d Cir. 1932): "[I]n most cases reasonable prudence is in fact common prudence; but strictly it is never its measure. . . Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission." *Id.* (emphasis added by the *Helling* court). Note that the facts of *Helling* fall

not determinative. The requirement that the doctor explain why he departed from the manufacturer's express instructions and warnings de-emphasizes customary practice. The jury focuses on the facts of the particular case and on the doctor who has, in fact, misused the product under the law of products liability.¹⁵⁴ Doctors should be held to the same standard in the use of prescription drugs, as consumers in the use of non-toxic products: they should read and heed warnings. If they depart from the instructions, doctors should be prepared to give a medically-sound explanation for that departure.¹⁵⁵

V. ARGUMENTS PRO AND CON

The medical profession has referred to evidentiary use of the package insert to establish the standard of care as a "therapeutic straight jacket."¹⁵⁶ Physicians claim that they rely primarily on their own experience and literature published by their colleagues to determine proper drug usage,¹⁵⁷ rather than the conservative and quickly outdated package inserts.¹⁵⁸ The inserts are considered outdated from the standpoint that there are many medically-sound uses for prescription drugs which are unapproved by the FDA.¹⁵⁹ The inserts are considered overly-conservative since they

within the common knowledge rule and that a lay jury could conclude, without expert testimony, that the custom was negligent. *Helling* was reaffirmed in *Gates v. Jensen*, 92 Wash. 2d 246, 595 P.2d 919 (1979). See also *Favolora v. Aetna Casualty & Surety Co.*, 144 So. 2d 544 (La. Ct. App. 1962) (Plaintiff fell during X-rays. The radiologist did not ask any questions and was not aware that part of the plaintiff's complaint was dizzy spells. According to the customary practice, taking the patient's history was not part of the radiologist's responsibility. The court found the customary practice negligent.); *Morgan v. Sheppard*, 91 Ohio App. 579, 188 N.E.2d 808 (1963) (Patient went into shock following surgery. The surgeon did not visit the patient for 12 hours because it was customary to deal with the problem by phone. Regardless of the custom the surgeon was liable for the death.).

154. See *supra* notes 30-32 and accompanying text. "The manufacturer of the drug should be liable for all reactions that are not the result of the physician's negligence, measured primarily by his deviation from the manufacturer's warnings and instructions . . ." Merrill, *supra* note 3, at 107-08.

155. 2 S. PEGALIS & H. WACHSMAN, *supra* note 2, at 9.12.

156. Hirsh, *supra* note 9, at 145.

157. *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 576, 317 P.2d 170, 180 (Cal. Dist. Ct. App. 1957). *Salgo* is the only apparent case, dealing with drug manufacturers' recommendations, which sets forth policy arguments against their evidentiary use. Other cases in which the courts deny admission focus on the fact that the package inserts are inadmissible hearsay. See *supra* notes 60-67 & 81-102 and accompanying text.

158. *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 576, 317 P.2d 170, 180 (Cal. Dist. Ct. App. 1957).

159. Comment, *supra* note 85, at 479, 491. In one survey 81 percent of the doctors polled approved prescribing drugs for uses unapproved by the FDA: 7 per-

are written by the manufacturer who must emphasize safeguards in order to minimize its own civil liability. Manufacturers often recommend frequent laboratory tests and clinical observation of the patient.¹⁶⁰ According to the medical profession, strict adherence simply is not feasible,¹⁶¹ nor is it wise. "[T]he miraculous developments which have taken place in the effective use of antibiotics and other drugs might never have been accomplished if physicians were required to follow blindly the suggestions of the manufacturers who prepare, but do not use them."¹⁶² Additionally, doctors fear that the jury will misinterpret, misapply, and misunderstand the inserts since they are written not for the lay person to comprehend, but for physicians and pharmacists.¹⁶³

The medical profession's concerns are legitimate; however, the profession overlooks the package insert's actual role in litigation and improperly discredits the significance of the package insert. If the package insert were introduced into evidence in every case of alleged negligence in the use of prescription drugs, without the aid of expert testimony, there certainly would be a potential for abuse by the lay jury. However, unless the facts of a case and the drug manufacturer's recommendations fall within the jury's common knowledge, the package insert should not be sufficient to establish a *prima facie* case.¹⁶⁴ If the facts and the package insert would not allow a layperson to determine negligence, expert testimony should be required.¹⁶⁵ Thus, the common knowledge rule will prevent misuse of the package insert.

Furthermore, the admissibility of the package insert as evidence of proper usage does not require doctors to practice "cook book"¹⁶⁶ medicine, nor does it require "blind adherence"¹⁶⁷ to the drug manufacturer's recommendations. The physician definitely

cent stated they prescribed drugs frequently for unapproved uses, 38 percent stated they sometimes did so, and 36 percent stated they seldom prescribed a drug for a use not approved by the FDA. *Id.* at 479 n.11.

160. Sagall, *supra* note 42, at 59. Doctors believe that drug manufacturers place excessive warnings in the package insert to avoid civil liability for failure to warn of possible adverse reactions. *Id.*

161. *Id.* at 59. Part of the medical profession's negative reaction to the use of the package inserts as evidence in medical malpractice cases may be caused, in part, by a fear of government control over the profession through FDA regulations. See generally Comment, *Package Inserts as Evidence*, *supra* note 33, at 415-18.

162. *Salgo*, 154 Cal. App. 2d 560, 576, 317 P.2d 170, 180 (Cal. Dist. Ct. App. 1957).

163. 6 J. WIGMORE, *supra* note 62, at § 1690; Comment, *supra* note 85, at 482; Comment, *Package Inserts as Evidence*, *supra* note 33, at 425.

164. See *supra* notes 116-142 and accompanying text.

165. Comment, *supra* note 85, at 482.

166. Comment, *Package Inserts as Evidence*, *supra* note 33, at 425.

167. *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 576, 317 P.2d 170, 180 (Cal. Dist. Ct. App. 1957).

has more information regarding his patient's individual needs and is in the best position to balance the risks of using the drug against the particular patient's needs.¹⁶⁸ The package insert is not meant to substitute for the thoughtful and careful use of a drug by an informed physician.¹⁶⁹ A rule by which the insert is admitted into evidence either as an exception to the rule against hearsay, or in combination with the common knowledge rule, would not impose absolute liability upon the physician for all injuries caused by departure from the drug manufacturer's recommendations.¹⁷⁰ It would require that the physician have a medically-sound reason for that departure.¹⁷¹ "[W]hen a physician prescribes a drug for a use not in the approved labeling, he invokes two responsibilities. One, he has to be well-informed about the drug, and two, base his use of it on a firm scientific rationale and sound medical studies."¹⁷²

It is reasonable to impose a burden of exoneration upon the doctor and allow the plaintiff to establish his *prima facie* case with a package insert,¹⁷³ since the doctor should know the reasons for his departure and he should have better access to expert testimony to support that departure,¹⁷⁴ than would the plaintiff.¹⁷⁵ If supported by sound medical reasons, a doctor could still prescribe a drug for an unapproved use,¹⁷⁶ and avoid civil liability. In any event, the physician could avoid the potential of all civil liability by simply requiring his patient to give "informed consent"¹⁷⁷ prior to

168. Merrill, *supra* note 3, at 104-05.

169. *Id.* at 53.

170. See *supra* notes 143-49 and accompanying text.

171. Hirsh, *supra* note 9, at 148; Comment, *supra* note 85, at 479.

172. Hirsh, *supra* note 9, at 146.

173. See *supra* notes 150-55 and accompanying text.

174. See Comment, *Package Inserts as Evidence*, *supra* note 33, at 439.

175. *Mulder v. Parke Davis & Co.*, 288 Minn. 332, 181 N.W.2d 882 (1970). "All too frequently, and perhaps understandably, practicing physicians are reluctant to testify against one another." *Id.* at 336, 181 N.W.2d at 885.

176. Hirsh, *supra* note 9, at 149.

177. Under the doctrine of informed consent, the doctor must disclose all "material risks" which may affect the patient's decision whether to forego the proposed therapy. If the doctor fails to disclose a material risk and the patient would have declined treatment if he had known of the risk, the doctor is liable for the adverse consequences, if they do, in fact, occur. See, e.g., *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972), *cert. denied*, 409 U.S. 1064 (1972); *Cobbs v. Grant*, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972); *Sard v. Hardy*, 281 Md. 432, 379 A.2d 1014 (1977); *Scott v. Bradford*, 606 P.2d 554 (Okla. 1979). The doctrine of informed consent is based on the philosophy that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body," *Schloendorff v. Society of New York Hosp.*, 211 N.Y. 125, 129, 105 N.E. 92, 93 (1914), and that "[t]rue consent to what happens to one's self is the informed exercise of choice." *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972). See generally Katz, *Informed Con-*

the administration of a drug for an unapproved use.¹⁷⁸ "The best defense a physician has is proof of complete informed patient consent."¹⁷⁹

Although physicians contend that they rely on their colleagues' articles to determine proper drug usage, this reliance is arguably misplaced, since the FDA has no jurisdiction over the authors of articles to ensure that they are scientifically sound.¹⁸⁰ The FDA considers the package insert the best source of drug information.¹⁸¹ The reliability of the insert is built into the preparation process¹⁸² since the information contained within the insert must be based on "substantial evidence"¹⁸³ to gain FDA approval.¹⁸⁴ In fact, the busy medical practitioner has no alternative but to rely heavily on the package insert or the PDR¹⁸⁵ and to follow the directions and warnings carefully.¹⁸⁶ The drug manufacturer is "presumed qualified" to give directions on the use of its product,¹⁸⁷ and

sent—A Fairy Tale?, 39 U. PITT. L. REV. 137 (1977); Plant, *The Decline of "Informed Consent"*, 35 WASH. & LEE L. REV. 91 (1978); Shartsis, *Informed Consent: Some Problems Revisited*, 51 NEB. L. REV. 527 (1972); Waltz & Scheuneman, *Informed Consent to Therapy*, 64 NW. U.L. REV. 628 (1970). If the package insert was admissible, it could be used to establish a material risk, and the doctor's failure to disclose that risk could be used to prove a breach of the doctor's duty to get informed consent.

178. See 2 S. PEGALIS & H. WACHSMAN, *supra* note 2, at § 9.12; Hirsh, *supra* note 9, at 149; Merrill, *supra* note 3, at 65; Pruzan, *supra* note 5, at 733-34; Comment, *Package Inserts as Evidence*, *supra* note 33, at 444.

179. Hirsh, *supra* note 9, at 147.

180. *Id.* at 146. See also 2 S. PEGALIS & H. WACHSMAN, *supra* note 2, at 221.

181. 2 S. PEGALIS & H. WACHSMAN, *supra* note 2, at 222.

182. Comment, *Package Inserts as Evidence*, *supra* note 33, at 449.

183. Hirsh, *supra* note 9, at 146. For a definition of "substantial evidence" in the context of the FDA regulatory scheme, see *supra* notes 36-39 and accompanying text. See also *Mueller v. Mueller*, 88 S.D. 446, 452, 221 N.W.2d 39, 42-43 (1974) (The court acknowledged that before a drug is allowed on the market, it is put to stringent tests as to its usefulness and possible side effects.).

184. See *supra* notes 33-48 and accompanying text. "It must be presumed that the medical profession recognizes the [FDA] as a standard authority with respect to its regulation of warnings that accompany medication." *Cornfeldt v. Tongen*, 262 N.W.2d 684, 703 (Minn. 1977).

185. *Mueller v. Mueller*, 88 S.D. 446, 452, 221 N.W.2d 39, 43 (1974). In *Mueller*, the court stated that "[n]o one would expect [the busy doctor] to stop his practice and conduct tests and experiments so that he could prescribe the drug solely from his own independent findings on its usefulness and possible side effects." *Id.* at 452, 221 N.W.2d at 43.

186. *Chrestman v. Kendall*, 247 Ark. 802, 809, 448 S.W.2d 22, 26 (1969); *Mulder v. Parke Davis & Co.*, 288 Minn. 332, 338, 181 N.W.2d 882, 887 (1970); *Mueller v. Mueller*, 88 S.D. 446, 452-53, 221 N.W.2d 39, 43 (1974) (every doctor who testified admitted to using the PDR as a guide in prescribing drugs).

187. *Julien v. Barker*, 75 Idaho 413, 423, 272 P.2d 718, 724 (1954). See also *Cornfeldt v. Tongen*, 262 N.W.2d 684, 703 (Minn. 1977); *Mulder v. Parke Davis & Co.*, 288 Minn. 332, 338, 181 N.W.2d 882, 887 (1970).

the drug is considered safe only if used as directed.¹⁸⁸ More drug injuries will certainly occur if the warnings are disregarded.¹⁸⁹ The medical profession's contention that the package inserts are quickly outdated, should be given little weight, in light of the manufacturer's continuing duty to warn under FDA regulations.¹⁹⁰ Furthermore, drug manufacturers have an added incentive to update inserts since compliance with the FDA requirements is viewed by the courts as only a minimal standard.¹⁹¹ The manufacturer must provide all necessary information for safe drug usage in order to avoid civil liability.¹⁹²

The medical profession cannot overlook its obligation to keep informed.¹⁹³ Judicial recognition of the drug manufacturer's recommendations will provide a needed incentive for doctors to become fully informed about a drug before they administer it.¹⁹⁴ "It is important that there should be no relaxation of incentives for the physician to make use of the added information that manufacturers might be induced to provide."¹⁹⁵ Indeed, the Federal Commission on Medical Malpractice recognizes the need for the medical profession to become more proficient in handling prescription drugs.¹⁹⁶

VI. CONCLUSION

The judiciary should recognize the drug manufacturer's recommendations as the best source of information on proper drug usage and admit the package insert, if relevant, as an exception to the rule against hearsay.¹⁹⁷ The exception to the hearsay rule is justified by necessity and the trustworthiness of the drug manufac-

188. *Mueller v. Mueller*, 88 S.D. 446, 452, 221 N.W.2d 39, 42 (1974).

189. *See supra* note 58 and accompanying text.

190. *See supra* notes 46-47 and accompanying text.

191. *Pruzan, supra* note 5, at 717.

192. *See supra* notes 27-29 and accompanying text. *See also* *Julien v. Barker*, 75 Idaho 413, 423, 272 P.2d 718, 724 (1954) ("[The drug manufacturer] bears the same liability for damages to users of this product that manufacturers generally bear for . . . failure to warn against danger involved in the use of the product.").

193. Comment, *supra* note 85, at 491.

194. *Merrill, supra* note 3, at 90.

195. *Id.* at 110.

196. REPORT OF THE SECRETARY'S COMM'N, *supra* note 1, at 60. The Recommendation of the Commission was that "clinical pharmacology . . . be required as part of an integrated program for teaching the basics of therapeutics to all medical and nursing students and that similar attention be given to the same subjects in post-graduate and continuing medical education curricula." *Id.* The Commission noted that the study of clinical pharmacology was elective in some medical schools. *Id.*

197. "This is but another example of accepting the scientific process in the search for truth instead of reliance upon the efficacy of an oath as a guaranty of

turer's recommendations, as supervised by the FDA. Although the package insert is currently considered a member of the medical treatise family, the courts should treat the insert as a separate species in their evidentiary rulings.

[Drug manufacturers' recommendations] are *not only admissible but essential* in determining the possible lack of care of a doctor where the issue involved is injury from the administration of a drug. *We see no reason for the courts to hesitate to use a standard so widely and favorably used in the medical profession.*¹⁹⁸

If the package insert is admissible on the issue of the proper standard of care, and the facts of the case and the manufacturer's recommendation fall within the common knowledge of the jury,¹⁹⁹ the physician's departure from the clear and explicit warnings or instructions of the drug manufacturer should establish the plaintiff's *prima facie* case, providing the departure caused the plaintiff's injuries. Any further requirement of expert testimony to establish customary administration or prescription of a drug would be mere surplusage.²⁰⁰ When a physician deviates from express warnings that even the jury can understand, he should be required to explain the reasons for his actions, and the physician should not be allowed to hide behind the protective shield of the hearsay rule. Moreover, the "common knowledge" restriction on the use of the drug manufacturer's recommendations to establish the medical standard of care and its breach will preserve the doctor's independent judgment and check the discretion of the jury, while still encouraging sound medical practice and protecting the patient's right to non-negligent treatment in the use of prescription drugs.²⁰¹

trustworthiness." *Lewandowski v. Preferred Risk Mut. Ins.*, 33 Wis. 2d 69, 76-77, 146 N.W.2d 505, 509 (1966).

198. *Mueller v. Mueller*, 88 S.D. 446, 453, 221 N.W.2d 39, 43 (1974) (emphasis added).

199. In cases involving injuries from prescription drugs, the most likely area to fall within the jury's common knowledge might be a doctor's failure to get the informed consent; this is when the doctor fails to describe either a material risk or a material side effect explained in the package insert prior to the administration of the drug. *See supra* notes 177-79 and accompanying text.

200. Comment, *Package Inserts as Evidence*, *supra* note 33, at 438.

201. *Id.* at 433, 450.